

PROPOSED CHANGES IN THE REGULATIONS

Title 3. California Code of Regulations

Sections 2676, 2681, 2735, and 2783

INITIAL STATEMENT OF REASONS/ POLICY STATEMENT OVERVIEW

Description of the Public Problem, Administrative Requirement, or Other Condition or Circumstances the Regulation is Intended to Address

These regulations are intended to address the obligation of the Department of Food and Agriculture to protect the agricultural industry by ensuring in every way possible a clean and wholesome supply of meat, milk, and eggs for the benefit of the consumer.

Specific Purpose

The specific purpose of each section is stated as follows:

Section 2676 provides for efficacy substantiation to verify the safety and effectiveness of drugs and food additives used in commercial feed.

Section 2681 requires that any commercial feed containing protein that is derived from prohibited mammalian tissue shall not be fed to ruminant animals and shall comply with the requirements as stated in the provisions of Title 21, Code of Federal Regulations, Parts 589.2000, April 1, 2001.

Section 2735 supplements the control of cottonseed products to ensure that these products are below the tolerance for aflatoxin B1 established in Section 2734(a)(6).

Section 2783 defines various cottonseed products and their composition.

The factual basis for the determination by the Department that the amendments of Sections 2676, 2681, 2735, and 2783 are necessary is as follows:

Section 2676, as currently stated, is burdensome to the industry. There have been no reported feed safety problems attributed to the use of mineral premix products that contain 272.4 milligrams per pound or less added selenium. Also, this requirement is more stringent than federal regulations for selenium.

Section 2681 contains an editorial error that contradicts the prohibited use of certain animal proteins in feed for ruminant animals. This Section was adopted to prohibit use of these proteins in feed for ruminant animals. This Section conforms to federal standards and incorporates by reference Title 21, Code of Federal Regulations, Parts 589.2000, April 1, 2001.

Section 2735, as currently stated, requires that cottonseed products originating outside of California, as a condition of entry be accompanied by a Certificate of Movement, Revision 5-97. The Certificate of Movement shall state the origin and

destination of cottonseed products and to the extent required within the state of origin such documents as required by that state, including, if so required, an analysis certificate showing the results of laboratory sampling and testing for aflatoxin B1, showing compliance with the aflatoxin B1 tolerances stated in 2734(a)(6). This regulation as stated does not allow the Department to stop the movement of cottonseed products into California that do not have proof of compliance with the aflatoxin B1 tolerance if shipments originate from a state that does not require testing for aflatoxin B1.

Whole cottonseed is an important and economical source of dietary energy, fat, and protein for the production of milk by dairy cattle in California. The availability of California and Arizona cottonseed is limited due to the decline in cotton production in the West. Drought conditions in 2002 in Australia resulted in less cotton and cottonseed production as well. Therefore, feed suppliers have been looking to other sources of cottonseed in the southeastern United States. Cotton production is susceptible to many environmental conditions that can render it unsuitable as an animal feed. For example, cotton production in the southeastern United States was affected by wet weather during the growing and harvest season, resulting in significant damage to cottonseed with a potential for aflatoxin B1 levels above the tolerance of 20 parts per billion. Dairy producers, nutritionists, veterinarians, and feed brokers are concerned that moisture levels greater than 13 percent result in physical damage in the form of mold, heating in the seed resulting in Maillard product (brown discoloration) and higher free fatty

acids in oil (20-27 percent relative to 2-12 percent). Cottonseed from the Southeast is shipped to California feed suppliers in railroad boxcars, and is the most significant source of whole cottonseed available to California dairies.

When consumed by dairy cows, aflatoxin B1 can have negative effects on animal health and is deposited in the milk they produce. Aflatoxin B1 is a known carcinogen with established tolerances in milk, nuts, and grain for human consumption. The Maillard product is the non-enzymatic reaction in the seed when proteins and carbohydrates combine, rendering them unavailable to the animal. Elevated concentration of free fatty acids in oil has potential effects on animal intake, digestion, and production. Other fat sources with elevated concentrations of free fatty acids have been shown to reduce dry matter intake, milk yield, and nutrient digestibility when fed to cattle. Although research is limited, a recent research trial indicates that whole cottonseed with greater than 18 percent free fatty acids, when fed to steers, alters their ability to digest feed.

Section 2735(b) requires distributors of cottonseed originating outside of California to prove compliance with California cottonseed regulations by mailing all required documents for review by the Department on or before the date of shipment. Also, a copy of all of these documents must accompany the lot to the purchaser. Currently, the industry interprets the word “accompany” as any means of providing these documents, including by fax. In most cases, the purchaser does not see the shipments physically; therefore, it is appropriate to

receive the documents via fax or, if possible, via e-mail. However, this creates confusion for the enforcement staff of the Department when inspecting railcars of cottonseed entering California. Specifying that documents shall be affixed to or accompany the shipment will allow inspection staff of the Department to more readily determine compliance with California's laboratory testing and certification requirements for cottonseed at the site of railcar delivery.

Section 2735(c) requires cottonseed products that originate from Riverside and Imperial Counties of California to be shipped to a Department-approved detoxification or oil extraction site unless the products are certified by laboratory testing showing that the product is within the tolerance for aflatoxin B1. The laboratory certifications shall be made available to the Secretary upon request. As stated, it is not required that laboratory certification be provided to the purchaser, which is inconsistent with the requirements for out-of-state shipments.

Existing Section 2735(d) elaborates on the sampling and analysis procedure for cottonseed products that enter California, and the notification of producers when analysis is in excess of the tolerance for aflatoxin B1. A notice of analysis sent to the producer shall advise of the opportunity to have a sample sufficient for analysis sent to a certified laboratory. It provides the opportunity for producers, within ten days from date of receipt of a violation, to request a reanalysis of a split sample at their own expense and by a laboratory of their own choosing. As stated, the industry interprets that a new sample from the original lot is to be

reanalyzed instead of a split of the sample originally collected by the Department staff. Also, there is no suggested resolution in this process based on the outcome of the reanalysis. Section 15080 of the Food and Agricultural Code was revised to clarify the appeal process for any seized or held lot found to be in violation. The revised law is now in conflict with this subsection. Under the new appeal process, a manufacturer or guarantor of a seized or held lot may appeal the result of analysis to the Secretary in writing within ten days of receiving the notice of violation. Upon receipt of the appeal, the Secretary shall perform an additional analysis of the official sample representing the lot in question. The cost of analysis shall be at the expense of the person that requests the appeal. The findings from the appeal analysis are final.

Section 2735(e)(3) provides for a mailing address within the Department where the Certificate of Movement of Cottonseed Products can be sent. The room number has changed in that address.

Section 2783 defines various types of cottonseed products. Subsection (j) defines whole cottonseed as seed remaining after the removal of fiber in the ginning process and requires that it be labeled to include the maximum percent ash. As defined, subsection (j) lacks specified standards of quality that can be associated with the wholesomeness and safety of whole cottonseed, including the presence of aflatoxin, or other deleterious substances such as mold.

The proposed amendment of Section 2676 revises subsection (c) by adding the words “more than” and deleting the words “or more.” This amendment would establish uniformity with the federal standards for selenium, requiring premises that contain more than 272.4 mg/lb added selenium to maintain a daily inventory record.

The proposed amendment of Section 2681 revises subsection (a) to clarify and correct an editorial error by deleting the words “for ruminant animals.” This amendment would ensure that commercial feeds containing prohibited mammalian tissues are not fed to ruminant animals.

The proposed amendment of Section 2735(a) reformats and revises subsection (a) as (a) (1)(2) and 2735 (b), and establishes a new subsection 2735(a)(3). This amendment would ensure all shipments of cottonseed products originating outside of California, as a condition of entry, will be accompanied by: (1) a completed Certificate of Movement (Rev. 5-97); (2) an analysis certificate reporting: a) results of sampling and laboratory testing verifying compliance with the 20 ppb or 300 ppb aflatoxin B1 tolerance; b) the name of the testing laboratory and report number representing the lot of cottonseed products identified on the Certificate of Movement; and (3) a label with a guaranteed analysis for percent ash, crude fat, fiber, protein, and all specifications included in the definitions of cottonseed products in Section 2783. The control of products

that do not meet the aflatoxin B1 tolerances is deferred to the new subsection 2735(b).

As a result of the proposed amendments to the previous subsection 2735(a), it is necessary to re-letter existing subsections 2735(b) and (c) to subsections 2735(c) and (d), respectively.

The proposed amendment of subsection 2735(b), re-lettered to subsection 2735(c), requires that documentation for shipments by railcar, truck, barge, container, ship or air transportation shall be affixed to or accompany the lot to the purchaser. This amendment would ensure that the purchaser receives a copy of all required documentation, and shipments can be adequately inspected at the border stations or at destination when entering the state.

The proposed amendment of subsection 2735(c), re-lettered to subsection 2735(d), requires that laboratory certifications shall accompany cottonseed products to the purchaser for shipments originating in Riverside and Imperial Counties. This amendment would ensure that certification of compliance with the tolerance for aflatoxin B1 is provided to purchasers of cottonseed products that originate from either outside the state or from areas of known risk of elevated aflatoxin within California.

The proposed deletion of existing subsection 2735(d) would remove a consistency problem between the process in the regulation for providing samples to producers for reanalysis and the appeal process in Section 15080 of Title 3, Food and Agricultural Code. This amendment would assert that the Department would be conforming to the appeal process stated in the Food and Agricultural Code, Section 15080.

The proposed amendment of subsection 2735(e)(3) deletes the room number in the address of the Department.

The proposed amendment of subsection 2783(j) revises the definition of whole cottonseed. This amendment would add quality standards associated with product wholesomeness, specifying maximum levels of free fatty acids in the oil, moisture, and foreign materials.

The proposed addition of subsection 2783(k) establishes a definition for prime whole cottonseed. This amendment would provide a definition that conforms to the Trading Rules of the National Cottonseed Products Association, and establishes uniformity with existing national standards and definitions of cottonseed products.

As a result of the proposed addition of subsection (k), it is necessary to re-letter the previous subsection 2783(k) to subsection 2783(l).

Estimated Cost or Savings to Public Agencies or Affected Private Individuals or Entities

The Department of Food and Agriculture has determined that these changes in Sections 2676, 2681, 2735, and 2783 do not impose a mandate on local agencies or school districts. The Department also has determined that no savings or increased costs to any state agency, no reimbursable costs or savings under Part 7 (commencing with Section 17500) of Division 4 of the Government Code to local agencies or school districts, no discretionary costs or savings to local agencies or school districts, and no costs or savings in federal funding to the State will result from the proposed action.

The cost impact of the changes in the regulation on private persons or businesses is expected to be insignificant.

Assessment

The Department has made an assessment that this amendment to the regulations would not: (1) create or eliminate jobs within California, (2) create new business or eliminate existing businesses within California, or (3) affect the expansion of business currently doing business within California.

Alternatives Considered

The Department of Food and Agriculture must determine that no alternative considered would be more effective in carrying out the purpose for which the

action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.